

## **CLAIMS**

- 1. A method for measuring the activation of an effector cell belonging to the immune system, which may or may not be transformed, by means of a monoclonal (MoAb) or polyclonal antibody characterized in that it comprises bringing CD16 receptor-expressing cells into contact in a reaction medium in the presence of the antibody and of the antigen for said antibody, and measuring the amount of at least one cytokine produced by the CD16 receptor-expressing cell.
- The method as claimed in claim 1, characterized in that the effector cell is a CD16 receptor-expressing
  Jurkat cell.
  - 3. The method as claimed in either of claims 1 and 2, characterized in that at least one cytokine selected from IL-1, IL-2, IL-3, IL-4, IL-5, IL-6, IL-7, TNF $\alpha$ , and IFN $\gamma$  is quantified.
  - 4. The method as claimed in one of claims 1 to 3, characterized in that the interleukin IL-2 is quantified.

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5. The method as claimed in one of claims 1 to 4, characterized in that the amount of cytokine produced is a marker for activation or for inhibition of effector cells.

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- 6. The method as claimed in one of claims 1 to 5, characterized in that the amount of interleukin IL2 secreted reflects the quality of the antibody bound by the CD16 receptor as regards its antigen-binding integrity (Fc function) and effectiveness (antigenic site).
- 7. The method as claimed in one of claims 1 to 6, characterized in that the amount of interleukin IL2

secreted is correlated with an ADCC-type activity.

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- 8. A method for evaluating the effectiveness of a monoclonal or polyclonal antibody, characterized in that it comprises bringing CD16 receptor-expressing effector cells of the immune system into contact in a reaction medium in the presence of an antibody and of the antigen for said antibody, and measuring the amount of at least one cytokine produced by the CD16 receptor-expressing cell.
  - 9. The method according to claim 8 to evaluate the efficacy of a polyclonal or monoclonal antibody with specificity to anti-Rh of human red blood cells.
- 10. A method for evaluating the ability of a cell to produce an effective monoclonal antibody, characterized in that it comprises bringing CD16 receptor-expressing effector cells of the immune system, which may or may not be transformed, into contact in a reaction medium in the presence of an antibody and of the antigen for said antibody, and measuring the amount of at least one cytokine produced by the CD16 receptor-expressing cell.
- 11. The method according to claim 10, wherein cells used for the production of therapeutic antibodies are selected from CHO, YB2/0, human lymphoblastoid cells, insect cells and murine myeloma cells or any other cells for expression.
- 12. A method for evaluating the effectiveness and the integrity of polyclonal antibodies after one or more purification steps, characterized in that it comprises bringing CD16 receptor-expressing effector cells of the immune system, which may or may not be transformed, into contact in a reaction medium in the presence of the purified antibody and of the antigen for said antibody, and measuring the amount of at least one cytokine produced by the CD16 receptor-expressing cell.

- 13. The method according to one of claims 1 to 8, wherein antibodies are selected from those for which an increase of more than 100%, 250%, 500% or 1000% in the amount of IL-2 release is observed compared with the control in the absence of antibody, or a given antibody as negative reference.
- 14. The method according to one of claims 1 to 13, wherein the reacting mixture comprises human 10 immunoglobulins (IVIgs).
  - 15. The use of the method according to one of claims 1 to 14, for the evaluation of MoAb production by transgenic plants or transgenic mammals.
  - 16. The use of the method according to one of claims 1 to 14, for selecting antibodies that are effective for a therapeutic treatment.
- 17. The use of the method according to one of claims 1 to 14, to evaluate the response ability of a patient effector cells in response to appropriate polyclonal or monoclonal antibody for his treatment.

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